

Remarks

Claims 1-58 are pending. Claims 1-58 are rejected.

Rejections under 35 U.S.C. § 103(a)

Claim 4 is rejected under 35 U.S.C. §103(a) as being obvious over Roby (WO 98/32398) in view of U.S. publication No. 2002/0107330 by Pinhcuck et al (“Pinhcuck”).

Claim 4 is drawn to a method of forming a coating on a medical device. The coating includes a PEA polymer and a low energy, surface blooming polymer, which has a PEA miscible block or PEA miscible backbone. The low energy, surface blooming polymer includes A and B blocks as defined in claim 4.

Roby discloses the preparation of a poly(ester amide) (PEA) polymer that can be used for fabrication of surgical devices. However, there is no teaching in Roby of a method of forming a coating comprising applying to an implantable device a composition that comprises a PEA polymer **and a low surface energy, surface blooming polymer** that includes a PEA miscible block or PEA miscible backbone. Nor does Roby recognize the need to improve the properties of a coating formed of a PEA polymer using **a low surface energy, surface blooming polymer**.

Pinhcuck discloses coatings that can be formed of a polymer that can include an A block and a B block. The A block can be a polyolefin, and the B block can be from a methacrylate monomer. Pinhcuck does not describe or teach using a polymer blend to form a coating. Nor does Pinhcuck recognize the need to improve the properties of a coating. Nor does Pinhcuck recognize that the properties of a coating including a PEA polymer can be improved using **a low surface energy, surface blooming polymer**.

Therefore, Roby and Pinhcuck each fail to provide motivation for a person of ordinary skill in the art to combine these two references. Even if they did, for argument purposes, Roby

and Pinhcuck would not lead a person of ordinary skill in the art to have a reasonable expectation of success of the subject matter of claim 4 since both Roby and Pinhcuck fail to recognize that the properties of a coating including a PEA polymer can be improved using **a low surface energy, surface blooming polymer**. As such, Roby and Pinhcuck would not make claim 4 *prima facie* obvious under 35 U.S.C. §103(a) (see MPEP §2141).

Claims 1-3, and 5-58 are rejected under 35 U.S.C. §103(a) as being obvious over Pacetti (WO 03/022323) in view of Roby.

Claim 1 defines a method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties. The method includes (a) applying to an implantable device a solution or suspension of a composition comprising **PEA** and **a low surface energy, surface blooming polymer**, and (b) forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer **includes a PEA miscible block or PEA miscible backbone**.

Pacetti describes a coating for reducing the release rate of a therapeutic agent from the coating. The coating includes a polymer capable of maintaining its crystalline lattice structure while the therapeutic agent is released from the coating. As the Examiner correctly notes, Pacetti does not describe a coating that includes a PEA. Nor does Pacetti describe or teach forming a coating comprising applying to an implantable device a composition that comprises a PEA polymer **and a low surface energy, surface blooming polymer** that includes a PEA miscible block or PEA miscible backbone. Nor does Pacetti recognize the need to improve the properties of a coating formed of a PEA polymer using **a low surface energy, surface blooming polymer**.

As discussed above, Roby discloses the preparation of a poly(ester amide) (PEA) polymer that can be used for fabrication of surgical devices. However, Roby does not describe or teach forming a coating comprising applying to an implantable device a composition that comprises a PEA polymer **and a low surface energy, surface blooming polymer** that includes a PEA miscible block or PEA miscible backbone. Nor does Roby recognize the need to improve the properties of a coating formed of a PEA polymer using **a low surface energy, surface blooming polymer**.

The Examiner alleges that Applicants own teaching that a polyurethane with a polydimethylsiloxane soft segment would meet the definition of the low energy, surface blooming polymer, thus rendering the claims of the instant application obvious. Applicants respectfully point out that polyurethane **WAS DELETED FROM THE CLAIMS** and is no longer relevant to the claims of the instant application.

In sum, Pacetti and Roby fail to teach or suggest each and every element of the coating defined by claim 1. Therefore, claim 1 is patentably allowable over Pacetti and Roby under 35 U.S.C. 103(a). Claims 2, 3 and 5-7 and 53 depend from claim 1 and are patentable over Pacetti and Roby under 35 U.S.C. 103(a) for at least the same reason.

Claim 8 defines a method of forming a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone. As discussed above, Pacetti and Roby fail to teach or suggest each and every element of the coating defined by claim 8. Therefore, claim 8 is patentably allowable over Pacetti and Roby under 35 U.S.C. 103(a). Claims 9-11 and 54 depend from claim 8 and are patentable over Pacetti and Roby under 35 U.S.C. 103(a) for at least the same reason.

Claim 12 defines coating composition for coating an implantable device. The composition comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone. As discussed above, Pacetti and Roby fail to teach or suggest each and every element of the coating defined by claim 12. Therefore, claim 12 is patentably allowable over Pacetti and Roby under 35 U.S.C. 103(a). Claims 13-18 and 55 depend from claim 12 and are patentable over Pacetti and Roby under 35 U.S.C. 103(a) for at least the same reason.

Claim 19 defines a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone. As the discussion of claim 8 shows, Pacetti and Roby fail to teach or suggest each and every element of the coating defined by claim 19. Therefore, claim 19 is patentably allowable over Pacetti and Roby under 35 U.S.C. 103(a). Claims 20-22 and 56 depend from claim 19 and are patentable over Pacetti and Roby under 35 U.S.C. 103(a) for at least the same reason.

Claim 23 defines an implantable device comprising a coating which comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone. As discussed above, Pacetti and Roby fail to teach or suggest each and every element of the coating defined by claim 23. Therefore, claim 23 is patentably allowable over Pacetti and Roby under 35 U.S.C. 103(a). Claims 24-29, 34-38, 41, 42, 45-49, 51 and 57 depend from claim 23 and are patentable over Pacetti and Roby under 35 U.S.C. 103(a) for at least the same reason.

Claim 30 defines an implantable device comprising a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone. As discussed above, Pacetti and Roby fail to teach or suggest each and every element of the coating defined by claim 30. Therefore, claim 30 is patentably allowable over Pacetti and Roby under 35 U.S.C. 103(a). Claims 31-33, 39, 40, 43, 44, 50, 52 and 58 depend from claim 30 and are patentable over Pacetti and Roby under 35 U.S.C. 103(a) for at least the same reason.

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

CONCLUSION

The present communication presents no new issue. Withdrawal of the rejection and allowance of all the claims are respectfully requested. **If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment.** If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

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Respectfully submitted,

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